

Application No. (if known): 10/643,003

Attorney Docket No.: 02291/100H204-US1

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Dkt. No. 02291/100H204-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Zhongming Zeng

Serial No.: 10/643,003

Filed: August 18, 2003

For: PHARMACEUTICAL COMPOSITIONS FOR PROMOTING THE GROWTH
OF GRAM-POSITIVE BACILLI AND INCREASING THE ACIDITY IN
VAGINA AND THE USE THEREOF

October 17, 2003

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate.)

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- ☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ B. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/577,858 filed May 24, 2000

Applicant Identifies these documents by attaching hereto copies of the forms PTO- 892 and PTO- 1449 from the files of the prior application(s) or a fresh PTO- 1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☒ 3. Cite No. CA is are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☒ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on pages _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

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[] 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[X] 5. Other information being provided for the examiner's consideration follows:

A European Search Report dated June 12, 2003, which issued during the prosecution of Applicant's European Patent Application No. EP 98 95 5312, which corresponds to the present application, is enclosed.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of' the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

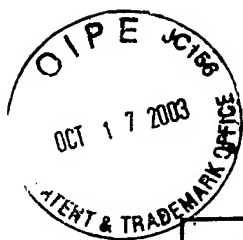
(1) U.S. Patent Application Serial No _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,


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for Howard M. Frankfurt 44085
Registration No. 32,613
Attorney for Applicant(s)

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PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|---|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/643,003 |
| | | | | Filing Date | August 18, 2003 |
| | | | | First Named Inventor | Zhongming Zeng |
| | | | | Art Unit | N/A |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 02291/100H204-US1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | BA | WO-89/05645-A1 | 06-29-1989 | Daniel BAR-SHALOM | | |
| | BB | WO-93/14773-A1 | 08-05-1993 | Rune Soremark | | |
| | BC | EP-0 242 459-B1 | 08-14-1991 | Showa Sangyo Co., Ltd. | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | CA | M.R. Guiraud, "Le Traitement Des Vulvo-Vaginites", Bourdeaux Medical, France, Vol. 11, No. 16, June 1978, pp. 1393-1400. | |
| | CB | B. Kaplan, et al., "Single-dose systemic oral fluconazole for the treatment of vaginal candidiasis", International Journal of Gynecology & Obstetrics, Vol. 57, No. 3, 1997, pp. 281-286. | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

SHEET 1 OF 1
(REV. 7-80)**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 2291/0H204-US0
APPLICANT: Zhongming ZENGSERIAL NO: 09/577,858
FILING DATE: May 24, 2000**U.S. PATENT DOCUMENTS**

*EXAMINER DOCUMENT

| <u>INITIALS</u> | <u>NUMBER</u> | <u>DATE</u> | <u>NAME</u> | <u>CLASS</u> | <u>SUBCLASS</u> | <u>FILING DATE</u> |
|-----------------|---------------|-------------|-------------|--------------|-----------------|--------------------|
|-----------------|---------------|-------------|-------------|--------------|-----------------|--------------------|

FOREIGN PATENT DOCUMENTS

| <u>*EXAMINER INITIALS</u> | <u>DOCUMENT NUMBER</u> | <u>DATE</u> | <u>COUNTRY</u> | <u>CLASS</u> | <u>SUBCLASS</u> | <u>TRANSLATION</u> | |
|-------------------------------|----------------------------|--------------|----------------|--------------|-----------------|--------------------|-----------|
| | | | | | | <u>YES</u> | <u>NO</u> |
| 1. | CN1104502 | Jul. 5, 1995 | CN | | | | X |

OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)***EXAMINER
INITIALS

EXAMINER: _____

DATE CONSIDERED: _____

*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 2291/0H204 SERIAL NO: 09/577,858
APPLICANT: Zhongming Zeng
FILED: May 24, 2000

U.S. PATENT DOCUMENTS

| <u>*EXAMINER INITIALS</u> | <u>DOCUMENT NUMBER</u> | <u>DATE</u> | <u>NAME</u> | <u>CLASS</u> | <u>SUBCLASS</u> | <u>FILING DATE</u> |
|-------------------------------|----------------------------|---------------|-------------|--------------|-----------------|--------------------|
| 1. | 3,860,707 | Jan. 14, 1975 | | | | |
| 2. | 5,518,733 | May 21, 1996 | | | | |

FOREIGN PATENT DOCUMENTS

| <u>*EXAMINER INITIALS</u> | <u>DOCUMENT NUMBER</u> | <u>DATE</u> | <u>COUNTRY</u> | <u>CLASS</u> | <u>SUBCLASS</u> | <u>TRANSLATION YES NO</u> |
|-------------------------------|----------------------------|-------------|----------------|--------------|-----------------|-------------------------------|
| 3. | 0 257 007 A1 | 24/2/88 | EPO | | | |
| 4. | 2 112 285 A | 20/7/83 | GB | | | |
| 5. | WO 94/02148 | 3/2/94 | PCT | | | |
| 6. | WO 94/03502 | 17/2/94 | PCT | | | |
| 7. | CN 1104502A | 7/5/95 | CN | | | |

OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER
INITIALS

8. Germain, Marc, et al., "Genital Flora in Pregnancy and Its Association With Intrauterine Growth Retardation";
J. Clin. Microbiol.; Vol. 32, No. 9; pp. 2162-2168 (Sept. 1994)

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 2291/0H204 SERIAL NO: 09/577,858
APPLICANT: Zhongming Zeng
FILED: May 24, 2000

9. McDonald, H.M., et al.; "Vaginal Infection and Preterm Labour"; *Br. J. Obstet Gynaecol*; Vol. 98, No. 5; pp. 427-435 (May 1991)
10. Thomason, Jessica L.; "Bacterial Vaginosis: Current Review With Indications for Asymptomatic Therapy"; *Am. J. Obstet Gynecol*; Vol. 165; No. 4, Part 2; pp. 1210-1217 (1991)
11. Hillier, Sharon, L.; "Efficacy of Intravaginal 0.75% Metronidazole Gel for the Treatment of Bacterial Vaginosis"; *Obstet-Gynecol*; Vol. 81, No. 6; pp. 963-967 (June 1993)
12. Hallén, Anders, Md., et al.; "Treatment of Bacterial Vaginosis With Lactobacilli"; *Sex-Transm-Dis.*; Vol. 19, No. 3; pp. 146-148 (May-Jun 1992)
13. Hughes, Viki, L.; "Microbiologic Characteristics of Lactobacillus Products Used for Colonization of the Vagina"; *Obstetrics & Gynecology*; Vol. 75, No. 2; pp. 244-248 (Feb. 1990)
14. Eschenbach, David, A.; "Bacterial Vaginosis and Anaerobes in Obstetric-Gynecologic Infection"; *Clinical Infectious Diseases*; Vol. 16; Supp. 4; pp. S282-S287 (1993)

EXAMINER: _____

DATE CONSIDERED: _____

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